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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,676	04/08/2002	Sam Fong Yau Li	2577-118	7819
6449 7590 12/20/2006 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		12/20/2006	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 12/20/2006.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/019,676	LI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-91,94,99 and 100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-91,94,99 and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 73-91, 94, 99, and 100 are pending and under consideration.
2. In the prior action, the Final action mailed on August 1, 2006, claims 73-91 and 94-100 under consideration and rejected.
3. In the Response of November 1, 2006, Applicant cancelled claims 95-98.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(Prior Rejection- Maintained)** Claims 73-91 and 94-100 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement with respect to the limitation in the claimed methods "wherein said contacting occurs without a prior washing step following the negative test." Claims 95-98 have been cancelled from the application. The rejection is therefore withdrawn from these claims.

In traversal of the rejection, the Applicant asserts that, although there was no explicit disclosure of such a limitation, such a disclosure was inherent in the silence of the application when discussing the re-usability of the crystals for a second test after a negative result. The Applicant indicates that this is in comparison to the regeneration of the crystal after a positive step, where washing does occur.

However, it is noted that the washing steps disclosed on pages 28 and 29 of the specification, with respect to the regeneration after a positive result, are not limited merely to

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washing. The regeneration involves subjecting the crystal to changes in conditions to remove antibody, or all compounds, from the surface of the crystal, and then subsequent washing. The purpose of the regeneration teachings are not that a simple washing would be required, but teaching that specific conditions may be used to remove bound analyte such that additional tests may be performed.

With respect to the washing after the negative result, while the application does not specifically teach such a use, the specification may still be considered to have provided adequate description for embodiments for which "one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." However, in the present case, the evidence indicates that those in the art would not have considered the use of such a method without a washing step to be in the Applicant's possession. This can be seen by the Applicant's own arguments in the April 3, 2006 Response. On pages 12-13 of that Response, Applicant asserted that the reuse of a crystal without washing "would not reasonably be expected to be successful" by those in the art. In addition, the Declaration of Dr. Yap (also submitted in April 2006, to demonstrate the non-obviousness of the claimed invention) stated on page 3 that the re-usability of the disclosed device without a washing step was "surprising." I.e., those in the art would not have expected such a method to work without a washing step.

In view of these arguments and statements, it is apparent that, without specific teachings to the contrary, those skilled in the art would have assumed the presence of a washing step. Thus, absent a specific teaching to the contrary, those in the art would have assumed the presence of such a washing step. In view of this, and because there was no such explicit teaching in the present application indicating that such a washing step was not required, the Applicant's

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arguments are not found persuasive. The rejection is therefore maintained against pending claims 73-91, 94, 99, and 100 for these reasons, and for the reasons of record.

Claim Rejections - 35 USC § 103

6. **(Prior Rejections- Withdrawn)** Claims 95 and 97 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Thorns (U.S. Patent 5,510,241) and of U.S. Patent 5,306,644. Claims 95-97 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Rajashekara et al. (WO 98/03656). Claim 98 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view of Masten et al., J Bacteriol 175: 5359-65 and in view of Protein Accession CAA78777. In view of the cancellation of these claims, the rejections are withdrawn.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

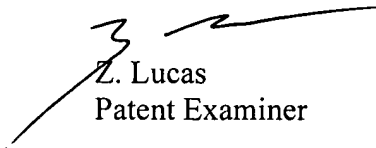
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



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